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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,325	07/12/2002	Tetutoshi Mithiue	KZ0445US(#90581)	1360
28672	7590	04/19/2005	EXAMINER	
D. PETER HOCHBERG CO. L.P.A. 1940 EAST 6TH STREET CLEVELAND, OH 44114			DESANTO, MATTHEW F	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Sp

Office Action Summary	Application No. 10/089,325	Applicant(s) MITHIUE ET AL.	
	Examiner Matthew F DeSanto	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 June 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>4/12/05</u> |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the liquid drip prevention mechanism and the non-return means must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 30 is objected to because of the following informalities: claim 30 is a duplicated claim (same as claim 21). Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
4. Claim 10, 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. With regards to claim 10, the applicant fails provide the proper support in the specification for the means plus function statement. The examiner could not find any support in the specification, as well as drawings to further show what element is being claimed.
6. With regards to claim 27, the claim is unclear and indefinite because claim 27 claims "the hub has on both side members for preventing the hub from rocking" is unclear since claim 27 depends from claim 11 and there is no structure being claimed that allows the hub to perform this function. Claim 11 discloses side members on the needle tube, but not on the hub. The examiner is unclear as the structure of the hub that performs this function.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-10, and 19-26, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suyeoka et al. (USPN 3,595,230) in view of Schoenberg (USPN 4,888,001).

Suyeoka et al. discloses an injection needle with an elliptical needle hub with a needle on the distal end, and a housing that encompasses the hub, wherein the housing has five sections. The five sections include a first reduced diameter, a first increasing diameter, a second reduced diameter, a second increasing diameter, and a third reduced diameter (Figure 1,2,10 and entire reference). Suyeoka et al. fails to disclose a pair of flexible wings.

Schoenberg discloses a needle injector with a pair of flexible wings that can cover the needle-housing member as well as have structure that will allow them to become immovably attached to each other (Figures 1-14 and entire reference).

At the time of the invention one of ordinary skill in the art would combine the invention of Suyeoka et al. with Schoenberg because Schoenberg taught the advantage of having wings, which are for easier manipulation of the needle device as well as a safety precaution during and after injecting (Schoenberg Column 1, lines 52-69, and Column 3, lines 55-69).

9. Claims 11-18, 27, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dillion et al. (USPN 5,833,670) and further in view of Schoenberg.

Dillion et al. discloses an injector needle with a needle tube, a hub for retaining the base end of the needle hub, a hollow needle, a guide tube joined to the hub, a hollow needle housing member including at least two expanded parts spaced via a reduced diameter part, but Dillion et al. fails to teach a set of wings on the needle injector.

Schoenberg discloses a needle injector with a pair of flexible wings that can cover the needle-housing member as well as have structure that will allow them to become immovably attached to each other (Figures 1-14 and entire reference).

At the time of the invention one of ordinary skill in the art would combine the invention of Dillion et al. with Schoenberg because Schoenberg taught the advantage of having wings, which are for easier manipulation of the needle device as well as a safety precaution during and after injecting (Schoenberg Column 1, lines 52-69, and Column 3, lines 55-69).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto
Art Unit 3763
April 12, 2005



NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
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